

Stem Cell Research Grant Program

An initiative of the New South Wales
and Victorian Government

Guidelines for Proposals for
NSW/VIC Government Stem Cell
Research Grant Program
2008



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Section 1

Overview of the NSW/VIC Government Stem Cell Research Grant Program

1.1 Introduction

In December 2006 the Commonwealth Government passed reforms to the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* which govern the use of human embryos in research, including stem cell research. These included changes to the techniques which are allowed to be undertaken under licence in Australia.

In May 2007 the Victorian Parliament passed legislative reforms consistent with the reforms in the Commonwealth. The NSW Parliament passed amendments to its legislation in June 2007 which aligns with the Commonwealth and Victorian reforms.

On the 6th August 2007, the NSW Premier, the Hon Morris Iemma MP and the NSW Minister for Science and Medical Research, the Hon Verity Firth MP announced a \$500,000 commitment for embryonic stem cell research to be undertaken using techniques now allowed under licence. In April 2008 the Victorian Government announced it would match this commitment and join with NSW in a partnership to promote stem cell research that is fully compliant with Australia's rigorous regulatory framework

By working together in this partnership the NSW and Victorian Governments aim to accelerate developments in stem cell research which has previously been constrained by legislation, in particular developing the techniques required to produce disease-specific stem cell lines. By accelerating such research the Stem Cell Research Grant Program will place NSW and Victorian researchers in a strong position to compete for further long term research funding domestically and internationally.

The NSW and Victorian Governments are inviting proposals for a program of research to improve the sustainability of techniques, technical expertise and the range of applications for stem cell research and in particular the advancement of somatic cell nuclear transfer (SCNT) techniques. The program of research should be substantially undertaken in NSW and Victoria however broader national and international collaboration is strongly encouraged. By working together the NSW and Victorian Governments are seeking to advance the field of stem cell research in a way which could not be achieved through projects in individual states and research institutions.

The Research Grant Program will support stem cell research which utilises techniques now allowed under the framework of the *Human Cloning and Other Prohibited Practices Amendment Act 2007* NSW and the *Infertility Treatment Amendment Act, 2007* VIC. The Acts are the NSW and VIC components of the nationally consistent scheme that prohibits human reproductive cloning and provides for certain types of research to occur.

Support will be in the form of one or more Grants up to a total of \$1,000,000 (exclusive of GST) over two years.

Allocation of funds will be negotiated with any successful applicants. The Stem Cell Research Grant Program will be jointly administered by the NSW Department of State and Regional Development through the Office for Science and Medical Research (OSMR) and the Victorian Department of Innovation, Industry and Regional Development (DIIRD).

1.2 Objectives

The Stem Cell Research Grant Program is designed to expand stem cell research in NSW and Victoria and to promote important and potentially beneficial research that may have a profound effect on serious and/or life threatening human diseases such as diabetes, Parkinson's disease, spinal cord injury, cystic fibrosis, mitochondrial disease, some forms of cancer and heart and eye disease.

The aim of the Research Grant Program is to:

- Support scientists working with adult as well as embryonic stem cells;
- Expand and accelerate the knowledge base and research capability to see advances made in the development of stem cell science including SCNT and other techniques in NSW and Victoria, nationally and internationally;
- Encourage the development of research that is of benefit to the community through addressing infertility and serious disease;
- Support research that will translate into economic, health, environmental and social benefits for NSW and Victoria; and
- Promote collaborative partnerships between NSW and Victoria.

1.3 Making a Grant

Grants are made on behalf of the NSW Government by the Minister for Science and Medical Research and on behalf of the Victorian Government by the Minister for Innovation, after considering the recommendations of the Stem Cell Research Grant Committee (see section 1.6.3), which is responsible for assessing all applications.

1.4 Use of Funds

The purpose of the Grant is to promote research which aims to alleviate human suffering through the development of treatments and cures for serious and life-threatening diseases and address infertility, including through the use of stem cell research using SCNT or other technologies

The allocation of funds will only support research undertaken within a strict regulatory framework, which adheres to all Australian laws applicable to this field of research.

Under the Stem Cell Research Grant Program, the total funding support will be limited to AUS \$1,000,000 (with a total approved project budget of at least \$1,000,000). A maximum of \$500,000 in funding support is available to institutions in each State. Funding will be provided to administering organisations based in NSW and Victoria.

1.5 Duration of Funding

Funding under the NSW/VIC Stem Cell Research Grant Program will be provided over 2 years.

1.6 Application and assessment process

1.6.1 Types of applications and forms

Applicants must use the relevant application form available from the NSW Office for Science and Medical Research website at www.osmr.nsw.gov.au or the Victorian Department of Innovation, Industry and Regional Development website at www.biotechnology.vic.gov.au

For a project to be eligible for funding it must involve at least one Victorian and one NSW based research institution with fairly balanced project work contributions. Researchers must demonstrate they have ready access to the infrastructure and other resources needed to complete their research projects.

Successful applicants will also enter a collaboration agreement with each other including details of management of future intellectual property resulting from the project. DIIRD and OSMR offices will monitor performance of all funded projects.

1.6.2 Overview of the application process

One copy of each application should be lodged to both State Government Departments by the lead research institutions on behalf of all research workers and collaborating organisations. For each application there must be a single administering institution responsible for projects within each state. The application will include the details of the partner organisation based in the other state and include details of the partner organisation's research project, contributions and research time table. The application should set out how all projects fit into a collaborative program of research. The application will be judged first by a three stage evaluation process including an expert assessment panel - independent from government.

1.6.3 All applicants

The lodging of an application for a Grant does not confer any entitlement upon the applicant. The making of a recommendation for a Grant is totally within the discretion of the Stem Cell Research Grant Committee. If none of the applications meet the standard of excellence required, the Committee reserves the right not to recommend support for an application for a Grant and the NSW and Victorian Governments reserve the right not to award a Grant.

The Stem Cell Research Grant Committee reserves the right to seek further information from applicants on their proposed research.

The Stem Cell Research Grant Committee requires its members to declare conflicts of interest and to withdraw from considering applications where such conflict exists.

1.6.4 Closing date and where to submit forms

The application for a NSW/VIC Stem Cell Research Grant must be received by close of business (AEST) on **Wednesday 7 May 2008**.

Applicants must:

- (i) Submit an e-mail copy and a signed hardcopy of the completed application and hard copies of any submitted ethics and license applications or approval certificates by mail or courier to both:

Nathan Rudder
The Secretariat
The Stem Cell Research Grant Committee
Office for Science and Medical Research
GPO Box 5477 Sydney NSW 2001 Australia
E-mail: Nathan.Rudder@osmr.nsw.gov.au

and

Dr Phil Davies
Office of Science and Technology
Department of Innovation Industry and Regional Development
121 Exhibition St Melbourne VIC 3000 Australia
E-mail: phil.davies@diird.vic.gov.au

1.7 Offer of Grant

Following approval by the NSW Minister for Science and Medical Research and the Victorian Minister for Innovation, the successful administering institution will be advised in a letter of offer.

The provision of the NSW/VIC Stem Cell Research Grant is conditional upon the administering institution having entered into a written agreement with the OSMR and DIIRD on behalf of the NSW and Victorian Governments. The agreement will cover the role of the institution and collaborating organisations if any, including:

- Contributions by all collaborating organisations.
- Intellectual property arrangements.
- An undertaking by the research organisations to abide by the conditions of the Grant as detailed in this document.

A condition of the agreement is that the two organisations must provide an agreement clearly stating their division and management of intellectual property that may arise from the research project.

1.8 Commencement of a Grant

The grant will commence upon the entering into of a written agreement between the administering institution and the Department of State and Regional Development on behalf of the NSW Government or Department of Innovation, Industry and Regional Development on behalf of the Victorian Government.

1.9 Acknowledgment of support by the NSW and VIC Government

All publications or discussion of results from research carried out with the assistance of a Grant must acknowledge the support of the Grant from the NSW and Victorian Governments.

Research workers may indicate their status as recipients of NSW/VIC Stem Cell Research Grant support in scientific publications and programs of scientific meetings and in any other public connection.

1.10 Contact point for further information

Enquiries about the NSW Stem Cell Research Grant Program may be addressed to:

Mr Nathan Rudder
Office for Science and Medical Research
GPO Box 5477 Sydney NSW 2001 Australia
E-mail: Nathan.Rudder@osmr.nsw.gov.au
Telephone: (02) 9338 6783

Or

Enquiries about the Victorian Stem Cell Research Grant Program may be addressed to:

Dr Phil Davies
Office of Science and Technology
Department of Innovation Industry and Regional Development
121 Exhibition St Melbourne VIC 3000
E-mail: phil.davies@diird.vic.gov.au
Telephone: (03) 965 19481

Section 2

Administration of the NSW/VIC Stem Cell Research Grants Program

2.1 Reporting requirements

The administering institution is required to submit regular progress reports detailing:

- Progress made in the research program.
- How the Grant funds were used.
- Progress on arrangements for ongoing support for the researcher and the research program in light of developments over the life of the Grant.
- Ethical compliance statements (per S 3.2.10 of these guidelines).
- Recipients who were not permanent residents or citizens at the time of taking up the Award: evidence of steps taken to secure permanent residency status.

OSMR or DIIRD reserves the right to recommend the suspension of the funding if progress is unsatisfactory or compliance with any of the above requirements are not met.

Any failure to comply with any legal or ethical requirements for undertaking stem cell research in Australia will result in the remainder of funds being withheld and may require all or part of the Research Grant being repaid. The requirement to comply with Australia's national stem cell legislation and NSW and Victorian Acts extends to all research partners both interstate or international. Failure by any research partner to meet regulatory requirements will result in the cessation of funds.

Research organisations will also be asked to collaborate in any evaluation of the Stem Cell Research Grants Program.

2.2 Failure to provide a report

Where an administering institution fails to submit a satisfactory report, as required, the Minister/s may determine that funds have not been used in accordance with conditions applicable to the Grant, and that all or part of the Grant must be repaid. In this case, the remainder of the administering institution's payments under the Stem Cell Research Grants may be withheld and/or action taken to recover Grant money.

2.3 Financial management — payments

The NSW/VIC Stem Cell Research Grant Program operates on a financial year basis. Subject to appropriations, regular payments will be made to the administering institution in accordance with the Grant Agreement. Funds must be used only for purposes approved under the grant scheme.

A NSW/VIC Stem Cell Research Grant is regarded as a "taxable supply" and therefore a Goods and Services Tax is payable. The NSW/VIC Stem Cell Research Grant will be increased by 10% and the administering institution will be required to collaborate in the recovery of the GST component. The grant agreement will therefore include the following clauses:

The Grant is subject to the GST. Gross funding for the Grant has been increased by 10% to reflect this and the Funded Organisation is liable to pay the GST on this funding. The Funded Organisation must forward its Australian Business Number ("ABN") to the Department at the commencement of this Agreement.

The Funded Organisation warrants that at the time of funding it is registered under GST legislation. The Funded Organisation will forward to the Department a tax invoice prior to the release of each payment in respect of the GST component. This will enable the Department, where entitled under the GST law,

to claim an input tax credit in respect of such GST. The quarterly payment inclusive of GST will be made shortly after receipt of the tax invoice.

2.4 Privacy of individuals

Documents containing personal information will be handled and protected in accordance with the provisions of the *Privacy Act 1988* (Cwth) *Privacy and Personal Information Protection Act 1998* (NSW) and *Information Privacy Act 2000* (Vic). Personal information would be disclosed only with permission of the individual to whom it relates or where the Acts allow.

Research workers and research organisations consent to the information supplied as part of their application being disclosed for the purposes of the assessment of their application and for purposes connected with the making and administration of the Grant. Such disclosure includes, but is not limited to, disclosure to members of the Stem Cell Research Grant Committee, independent readers/assessors requested by the Committee to provide advice, and relevant representatives and employees of Governments involved in the Grant process.

Research workers and research organisations acknowledge that announcement of the Grant will involve the dissemination of information to the public about the general nature of the research being funded and the research workers involved in the research project and the research organisations at which the research is being carried out.

2.5 Confidentiality

Information contained in applications will be regarded as confidential unless otherwise stated by the OSMR or DIIRD.

2.6 Intellectual property

Organisations must adhere to an intellectual property policy approved by their governing bodies that is congruent with the document “National Principles of Intellectual Property Management for Publicly Funded Research” released in September 2001.¹ A necessary requirement for successful applicants is that the funded research organisations provide an intellectual property agreement disclosing how any potential intellectual property rights will be managed between the organisations.

2.7 Incomplete or misleading information

It is the responsibility of the applicant to ensure that applications are complete in every particular. If an application is incomplete, the Committee may exclude it from further consideration. It is completely within the Committee’s discretion as to whether it will exclude an incomplete application, or request the applicant to furnish further information after the closing date.

If any application is found to have been intentionally completed (or failed to be completed) in such a way as to mislead the Committee, or is otherwise false or misleading in any material respect, the applicant will be disqualified from the Grant Program. The Committee may also refer the application to relevant authorities for consideration of appropriate action under State or Commonwealth law.

¹ These Principles were developed by a working group comprising: The National Health and Medical Research Council (NHMRC); the Australia Research Council (ARC); the Australian Tertiary Institutions Commercial Companies Association (ATICCA); the Australian Vice-Chancellors’ Committee (AVCC); the Department of Education, Training and Youth Affairs (DETYA); the Department of Industry, Science and Resources (DISR); and IP Australia.

Examples of the provision of false or misleading information that would result in an application being disqualified include providing fictitious track records and falsifying claims in publications records (such as describing a paper as accepted for publication when it has only been submitted).

Section 3

Application for the NSW/VIC Stem Cell Research Grant

3.1 Minimum eligibility criteria

Minimum eligibility criteria apply to the program of research and the research organisation(s).

Before completing the joint application form, the research organisation(s) should confirm their eligibility to apply for the NSW/VIC Stem Cell Research Grant Program by checking that they meet all of the following minimum criteria 3.1.1-3.1.10.

Joint application

3.1.1 The application is a joint application from two or more organisations that satisfy the other criteria below.

The Program of Research

3.1.2 Has been agreed between the research worker/s and the research organisation(s).

3.1.3 Includes a mature research plan.

3.1.4 Has a significant proportion of research to be undertaken in NSW and Victoria.

3.1.5 Includes details of the partner organisation(s) based in the other state, including its proposed research plan, contribution to the overall program of research and research timetable.

3.1.6 Must comply with all State and Australian ethical and legislative requirements. Appropriate evidence of relevant committee approval (for example Human Research Ethics Committee, Animal Experimentation Ethics Committee, NH&MRC Embryo Research Licensing Committee or Biosafety Committee) must be included in the application, or if not available, the details of the expected time when these approvals will be obtained should be supplied to the respective Government agency.

The research organisation or organisations

3.1.7 Are publicly funded research organisations in New South Wales and/or Victoria, Cooperative Research Centres or businesses in formal partnership with publicly funded organisations.

3.1.8 Have negotiated with the research worker/s a package covering her/his remuneration and funding for the agreed program of research.

3.1.9 Have nominated an administering institution in NSW and Victoria.

3.1.10 Have access to appropriate facilities for undertaking stem cell research that comply with all relevant legislation.

3.2 Additional assessment criteria

3.2.1 Applications meeting the minimum criteria will then be assessed against ALL of the following criteria 3.2.1-3.2.11. The information requested is designed to enable applications to be scored and ranked according to the assessment criteria:

- (i) Track record of research staff relative to opportunity.
- (ii) Proposed Research Program (*including feasibility, significance and innovation, approach, and benefit to NSW/VIC*).
- (iii) Contribution and support by the administering institution.
- (iv) Level of collaboration and contribution to an overall program of research.

Research workers

3.2.2 All Chief Investigators must:

- be an Australian citizen or have permanent residency status.
- hold an appointment at the administering or partner institutions.

- have access to appropriate facilities to conduct the research program.
 - not be named as an CI on more than 2 applications to the Stem Cell Research Grant Program.
- 3.2.2 Provide a statement of significant contributions to the research field.
- 3.2.3 Provide a track record/research achievements, including:
- Outline of all publications in the past five years.
 - Original articles in refereed journals.
 - Other publications.
 - Five career-best publications.
 - Status of patent applications.
- 3.2.4 Provide evidence of competitive funding awarded in the past five years.
- 3.2.5 Provide evidence of access to the infrastructure and resources needed to complete their research project.

Proposed program of research

The evaluation of the proposed program of research will be based on the format used for national grant agencies, namely:

- 3.2.6 Feasibility
- Proposed research is able to be undertaken within available facilities and within legislative requirements.
 - Likelihood of proposed research outcomes being achieved within proposed budget and timeframe.
- 3.2.7 Significance and innovation
- The research addresses an important problem.
 - The anticipated outcomes will advance the knowledge base of stem cell science and/or generation of disease-specific stem cell lines.
 - The program aims and concepts are novel and innovative.
 - New methodologies or technologies will be or are being developed, including use of stem cell applications now allowed under NSW and VIC legislation.
- 3.2.8 Approach
- The conceptual framework, design, methods and analyses are adequately developed, well integrated and appropriate to the aims of the program.
- 3.2.9 Benefit to NSW and Victoria
- The research program has the potential to translate into health, economic, environmental or social benefits for New South Wales and Victoria.
 - The research program will advance the knowledge of stem cell science and the practice and application of stem cell techniques nationally and internationally.
 - The research program shows clear evidence of a balanced partnership between organisations based in both NSW and Victoria.

Preference will be given to applications undertaking research that was previously prohibited but are now permitted under the *Human Cloning and Other Prohibited Practices Amendment Act 2007* and the *Infertility Treatment Amendment Act 2007*.

Research organisation contribution and support

- 3.2.10 The research and any other organisation(s) and the administering institution have given a firm commitment to:
- Providing the facilities and services necessary for the efficient conduct of the research.
 - Meeting the normal overhead expenses and normal institutional maintenance charges.

- Ensuring that the research staff will in no way be prejudiced in having access to such assistance as is normally provided by that institution to members of staff employed at a similar level.
- Providing annual Statements of Certification and Compliance in relation to human and animal ethics approval, NH&MRC Embryo Research Licensing and the Australian Code for the Responsible Conduct of Research 2007.

The Stem Cell Research Grant Committee **will not recommend an applicant** for a grant where it judges the level of support (in cash or in kind) is not adequate, even where the calibre of the research worker/s and the intended program of work are excellent.

Level of collaboration and overall program of research

3.2.11 The degree of collaboration between participating organisations and the extent to which projects within collaborating organisations contribute to an overall program of research which increases the technical knowledge and expertise on stem cell research in NSW and Victoria.

3.3 Application Format

The NSW/VIC Stem Cell Research Grant application form must be used and can be obtained from the OSMR (www.osmr.nsw.gov.au) or DIIRD (www.biotechnology.vic.gov.au) websites.